DEC 2 7 2000 K001738

## SUMMARY OF SAFETY AND EFFECTIVENESS

**NAME OF SPONSOR:** DePuy, Inc.
P.O. Box 988
Warsaw, Indiana 46581-0988

**510(k) CONTACT:** Marcia J. Arentz
Senior Regulatory Associate

**TRADE NAME:** DePuy Restore® Orthobiologic Soft Tissue Implant

**COMMON NAME:** Surgical Mesh
**CLASSIFICATION:** 878.3300 – Surgical Mesh
**DEVICE PRODUCT CODE:** 79 FTM

**SUBSTANTIALLY EQUIVALENT DEVICES:**

- Cook Biotech Inc. Surgisis Surgical Mesh (K980431)
- Cook Biotech Inc. SIS Wound Dressing (K973170)
- Cook Biotech Inc. SIS Wound Dressing II (K993948)
- Cook Biotech Inc. Surgisis Sling (K992159)
- Bio-Vascular Peri-guard (K983162)
- Bio-Vascular Peri-Strips (K992159)
- Organogenesis Graft Patch (K970561)
- Sentron SIS Hernia Repair Device (K974540)

**DEVICE DESCRIPTION AND INTENDED USE:**
The Restore Orthobiologic Soft Tissue Implant is a round device, manufactured from 10 plys of Small Intestine Submucosa, (SIS). SIS is a biomaterial derived from porcine small intestine. SIS is composed predominately of water and collagen. This material is identical to the material approved K982330 for use in general surgical procedures for reinforcement of soft tissue where weakness exists.

The Restore Orthobiologic Soft Tissue Implant is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists. The device is intended to act as a resorbable scaffold that initially has sufficient strength to assist with a soft tissue repair, but then resorbs and is replaced by the patient's own tissue. The device is also intended for reinforcement of the soft tissues which are repaired by suture or suture anchors, limited to the supraspinatus, during rotator cuff repair surgery.

**BASIS OF SUBSTANTIAL EQUIVALENCE:**
The DePuy Restore Orthobiologic Soft Tissue Implant is substantially equivalent to the above listed devices in that it is manufactured from the same material (SIS, porcine small intestine submucosa) as the Sentron SIS Hernia Repair Device and the Cook Biotech Inc. SIS Wound Dressing and SIS Surgical Mesh and Sling. The material is very similar to that of the Organogenesis Graft Patch (cross-linked porcine collagen). It has the same general intended use as the Organogenesis Graft Patch, the Bio-Vascular Supple Peri-guard, and the SIS Surgical Mesh and it has a similar design to all of these soft tissue patches. It has the additional specific intended use for reinforcement of the soft tissues which are repaired by suture or suture anchors during rotator cuff repair surgery which is substantially equivalent to the pre-amendment use of surgical mesh in rotator cuff repair.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 2000

Ms. Marcia J. Arentz
Senior Regulatory Associate
Depuy Orthopaedics, Inc.
P.O. Box 988
Warsaw, Indiana 46581

Re: K001738
Trade Name: Restore® Orthobiologic Soft Tissue Implant
Regulatory Class: II
Product Code: FTM
Dated: October 20, 2000
Received: October 23, 2000

Dear Ms. Arentz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001138

510(k) Number (if known)

Device Name Restore® Orthobiologic Soft Tissue Implant

Indications for Use:

The DePuy Restore Orthobiologic Soft Tissue Implant is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists. In addition, the implant is intended for use in the specific application of reinforcement of the soft tissues which are repaired by suture or suture anchors limited to the supraspinatus during rotator cuff repair surgery.

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Concurrence of CDRH, Office of Device Evaluation

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001738